UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,862	07/17/2003	Alfonso Ganan-Calvo	AERX-063CON4	6410

24353 7590 01/11/2006

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
LEWIS, AARON J	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,862	GANAN-CALVO, ALFONSO	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/27/2005 (AMENDMENT)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21,22,25-29,31,32,34,36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer ('161) in view of Fischer et al. ('663).

As to claim 21, Farmer discloses a method of delivering an aerosol to a patient, comprising: forcing a pharmaceutically active liquid through a channel (8) of a feeding source in a manner which causes the liquid to be expelled from an exit opening (figs.1,3,5) of the feeding source; forcing a gas through a pressure chamber (10) in a manner which causes the gas to exit the pressure chamber from an exit orifice (figs.1,3,5) in front (i.e. exit opening for gas is illustrated as being in front of exit opening for liquid medicament in figs.1,3,5) of a flow path of the liquid expelled from the exit opening of the feeding source; forming a stable liquid-gas interface between the liquid and the gas whereby the gas surrounds and focuses the liquid into a stable liquid jet focused on the first exit orifice of the pressure chamber. Figs.1,3,5 illustrates gas surrounding the liquid exit orifice and expressly disclosed as forming a partial vacuum to induce liquid therethrough at page 1, lines 77-87; accordingly, the gas focuses the liquid into a stable liquid jet focused on the exit orifice and allowing the stable liquid jet exiting the exit orifice to form evenly shaped drops.

To the extent, if any, that Farmer may not disclose the step of allowing the stable liquid jet exiting the exit orifice to form evenly shaped drops, resort is had to Fischer et al. in a method of aerosolizing a liquid, which teach angling the liquid exit orifice for the purpose of optimizing contact between a gas stream and the liquid thereby generating a more uniform aerosol of evenly shaped drops (figs.2 and 3; col.2, lines 32-46).

It would have been obvious to modify the shape of the liquid exit orifice of Farmer because it would have optimized contact between a gas stream and the liquid thereby generating a more uniform aerosol of evenly shaped drops as taught by Fischer et al..

As to claim 22, the particular medicament that is selected to be nebulized using the device and method disclosed by Farmer as modified by Fischer et al. includes a variety of medicaments having varying viscosities. The viscosity of a chosen medicament can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular viscosity.

As to claims 25, the diameters of the exit port and exit orifice (figs.1,3,5 of Farmer) can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameter including 0.002 to about 2mm. One of ordinary skill would realize the necessity of modifying the diameters of the ports in order to control the relative amounts of gas and medicament being aserosolized, which amounts vary in dependence upon the patient's age, size and physical condition.

As to claims 26 and 27, the diameters of the channels (2 and 3 of Farmer) can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameter including 0.01 to about 0.4mm. One of ordinary

skill would realize the necessity of modifying the diameters of the channels in order to control the relative amounts of gas and medicament being aserosolized, which amounts vary in dependence upon the patient's age, size and physical condition. Further, the spacing between the gas exit opening and liquid exit opening as illustrated in figs.1,3,5 of Farmer is closely spaced. The particular spacing can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular spacing including 0.002mm to 2.0mm. One of ordinary skill would realize the necessity of controlling this spacing in order to control the strength of aspiration of liquid medicament in an effort to control the concentration of medicament being delivered to a patient.

As to claim 28, Farmer as modified by Fischer et al. as discussed above with respect to claim 21 also teach forming aerosolized particles having a size in the range of about 0.1 micron to about 10 microns (see #25 of fig.3 of Fischer et al.).

As to claim 29, the particular medicament that is selected to be nebulized using the device and method disclosed by Farmer includes a variety of medicaments having varying viscosities. The viscosity of a chosen medicament can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular viscosity.

As to claims 31 and 32, in Farmer (figs.1,3,5) the gas from the pressure chamber surrounds liquid exiting the feeding source outlet which liquid is drawn into the orifice concentrically being focused by the gas flowing out of the outlet, and further wherein the

aerosolized particles are uniform in size to the extent of having a relative size standard deviation of 3 to 30% (see #25 of fig.3 of Fischer et al.).

As to claim 34, figs.1,3,5 of Farmer illustrates the liquid being accelerated by tangential sweeping forces exerted by the gas flowing on a surface of the liquid gradually decreasing a cross-section of the liquid forming a microjet.

As to claim 36, the liquid formulation of Farmer includes water (page 1, lines 9-10).

3. Claims 23,24,30,33,35,37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer ('161) in view of Fischer et al.('663) as applied to claims 21,22,25-29,31,32,34,36 above, and further in view of Knight et al. ('911).

The difference between Farmer as modified by Fischer et al. and claim 23 is the step of forcing the gas through the pressure chamber at a rate in the range of from about 50m/sec. to about 2000m/sec.

Knight et al., in a method of delivering an aerosol to a patient, teach a pressure regulator (14) for controlling pressure and flow of gas to pressure chamber (28).

It would have been obvious to modify Farmer to employ a pressure regulator (14) to achieve any desired pressure and flow including 0.01 nl/sec to about 100 microliter/sec. and forced through the opening of the pressure chamber at a rate in the range of from about 50-2000 m/sec..

Claim 24 is substantially equivalent in scope to claim 23 and is included in Farmer as further modified by Knight et al. for the reasons set forth above with respect to claim 23.

Claim 30 is substantially equivalent in scope to claim 23 and is included in Farmer as further modified by Knight et al. for the reasons set forth above with respect to claim 23.

As to claim 33, Knight et al. as discussed above, disclose the generation of a steady stream of small particles 95% of which are less than 5 microns in diameter. Since the vast majority, 95% of these particles, are less than 5 microns in size, the overall droplet size would have been considered as uniform by one of ordinary skill and any size deviation is within the claimed size standard deviation of 3-30%; further, disclosed particle size less than 5 microns falls within the claimed size range of 1-5 microns.

As to claim 35, Knight et al. disclose inhaling particles via mask (50).

As to claim 37, Farmer as further modified by Knight et al. also teach inhaling the drops of medicament. As to the claimed range of viscosities (0.0004 to 1kg/m/sec) of the formulation, the particular medicament that is selected to be nebulized using the device and method of Farmer as further modified by Knight et al. includes a variety of medicaments having varying viscosities. The viscosity of a chosen medicament can be arrived at through mere routine obvious experimentation and observation with no criticality seen (i.e. applicant has not disclosed criticality for any particular range of viscosities) in any particular viscosity. Further, inasmuch as the medicaments administered to a patient's respiratory tract may be intended for administration to any portion of the respiratory tract from pharynx to alveoli, it stands to reason that the viscosity of the particular medicament employed would have to be selected so that it would deposit at a desired point.

Claims 38 and 39 are substantially equivalent in scope to claims 23-24 and are included in Farmer as further modified by Knight et al. for the reasons set forth above with respect to claims 23-24.

As to claims 40-42, the diameters of the channels (2 and 3 of Farmer) can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameter including 0.01 to about 0.4mm. One of ordinary skill would realize the necessity of modifying the diameters of the channels in order to control the relative amounts of gas and medicament being aserosolized, which amounts vary in dependence upon the patient's age, size and physical condition. Further, the spacing between the gas exit opening and liquid exit opening as illustrated in figs.1,3,5 of Farmer is closely spaced. The particular spacing can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular spacing including 0.002mm to 2.0mm. One of ordinary skill would realize the necessity of controlling this spacing in order to control the strength of aspiration of liquid medicament in an effort to control the concentration of medicament being delivered to a patient.

Response to Arguments

4. Applicant's arguments with respect to claims 21-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
January 09, 2006